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November 3, 1999

Heather Rosecrans
Documents Management Branch (HFA-305)
Food & Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

3187 '99 NOV -5 A9:13

RE: Docket No. 99N-2210
Reclassification of Goniometer Devices to Class II

Dear Ms. Rosecrans:

This letter is submitted by Paladin Medical, Inc., on behalf of The Saunders Group. (The original official correspondent, Mr. Terry Mills, has left the company. I have been asked to make comments since I produced the submission on his behalf.)

The Saunders Group holds a 510(k) for the Saunders Electronic Inclinometer [(K943898)-Procode KQX, Class I]. The reason for our comments is to request that the reclassification of goniometers to Class II, specifically exclude goniometers that are battery powered.

During the review of The Saunders Electronic Inclinometer 510(k), the FDA reviewer at ODE at the time, insisted that The Saunders Electronic Inclinometer belonged in the powered goniometer classification CFR §888.1500. We attempted to convince the reviewer that the electronic inclinometer belonged in the non-powered goniometer classification of CFR §888.1520. He indicated that only non-powered, meaning non-electrical, goniometers could go into the non-powered classification. He said that since it combined both electronic and mechanical functions, The Saunders Electronic Inclinometer would have to be reviewed under CFR §888.1500. We still contend that The Saunders Electronic Inclinometer should be considered a non-powered goniometer.

The experience with this 510(k) illustrated that the definition of a "goniometer" (AC-powered) needs better definition. If FDA reclassifies all goniometers that have 510(k)s under the classification of CFR §888.1500 and procode KQX, as Class II devices, this would be a gross injustice. Battery-powered electronic inclinometers may use battery power for the LED display or to compute angles. There is no risk of shock to the patient, and there is no electrical lead with which to access AC-power. Therefore, in considering the reclassification of goniometers to Class II, we strongly urge FDA to review past cleared devices under this classification to delineate any device that may be battery powered as "non-powered" (CFR §

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888.1520). We further urge FDA to clarify by definition in the classification of CFR §888.1520, that non-powered goniometers include battery powered devices where the power is used for display or electronic calculation purposes. Certainly, electronic measuring and calculating devices are commonly found in hardware stores and use the similar technology. Such devices do not constitute a safety risk to users. Nor do such devices constitute a safety risk for a patient in this medical application.

We urge FDA to consider carefully the justification for reclassification of goniometers to Class II. FDA has presumed that all devices that have been cleared by FDA in CFR §888.1500, or which may be cleared in the future, using any form of electrical power, represent a hazard to the patient. It should be obvious that only those powered with alternating current, such as 110 or 220 volt devices, which connect directly to a power source, could constitute a voltage hazard to a patient. No battery powered device which uses batteries either to calculate the angle or display the information should be considered to represent a hazard of electrocution for a patient.

In Summary:

1. We feel the proposal to reclassify goniometers that have been cleared under CFR §888.1500 to Class II devices does not sufficiently delineate the description or the type of product that represents a risk to patient health and safety; and that due to past reviewer interpretation of "powered", FDA must differentiate between AC-powered and battery-powered products.

2. We urge FDA to distinguish between battery-powered goniometers and AC-powered goniometers more effectively; so, that battery-powered goniometer is considered a non-powered goniometer and is classified as CFR §888.1520.

3. We further recommend that CFR §888.1520 be retitled as "non AC goniometers" and identified as either mechanical devices, devices that use battery power as a means of measurement or display, or a combination of battery and mechanical, as long as they are not directly rechargeable or accessible to AC-power.

If you have any questions about the original 510(k) submission, or The Saunders Electronic Inclinometer, please feel free to contact me, Elaine Duncan, Paladin Medical, Inc., PO Box 560, Stillwater, MN 55082. Our phone number is 715-549-6035, fax-715-549-5380.

Sincerely,

Elaine Duncan, M.S.M.E., RAC
President, Paladin Medical®, Inc.
Consultant to The Saunders Group

C: Robin Saunders – The Saunders Group
Glenn Meidl – The Saunders Group

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2 Your Internal Billing Reference Information Saunders

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